UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,805	06/05/2001	Jeffrey Wheeler	INEX.P-010	5995

21121 7590 10/03/2002

OPPEDAHL AND LARSON LLP
P O BOX 5068
DILLON, CO 80435-5068

EXAMINER	
EPPS, JANET L	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/03/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/875,805	Applicant(s) WHEELER ET AL.	
	Examiner Janet L. Epps-Ford	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-6, and 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al.

The instant claims are drawn to methods for preventing particle aggregation of lipid:nucleic acid complex particles or preparing a lipid:nucleic acid complex, wherein said methods comprise incorporating a non-cationic lipid into a lipid:nucleic acid ccomplex, wherein the non-cationic lipid is a polyethylene glycol-based polymer. Additionally, the instant claims recite wherein the amount of the additional lipid (assuming Applicant is referring to the non-cationic lipid added to the lipid:nucleic acid complex) is from 1 to 15% of the particles, and wherein the lipid:nucleic acid is complex is lyophilized.

Choi et al. disclose PEG (polyethylene glycol)-modified ceramide lipids wherein said lipids enhance the properties of liposomes by increasing the circulation longevity or lifetime of the liposome; prevent aggregation of the liposomes during covalent protein coupling, such as for

targeting; preventing aggregation of liposomes incorporating targeting moieties or drugs, such as antibodies, and DNA (col. 4, lines 28-33). The liposome compositions of Choi et al. will typically comprise about 5 to about 30 mol % of the final liposome construction, but can comprise about 0.0 to about 60 mol % or about 0.5 to about 5 mol %, wherein the preferred lipid compositions are those wherein a drug or a biological agent is encapsulated within the liposome (col. 3, lines 5-15). The compositions of Choi et al. may be sterilized by conventional, well-known sterilization techniques, or may be sterile filtered. The resulting aqueous solutions may be packaged for use as is, or lyophilized; the lyophilized preparation being combined with a sterile aqueous solution prior to administration (col. 17, lines 30-47).

Choi et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 14-19, and 24-26 of U.S. Patent No. 5,981,501 ('501).

The instant claims are drawn to methods for preventing particle aggregation of lipid:nucleic acid complex particles or preparing a lipid:nucleic acid complex, wherein said methods comprise incorporating a non-cationic lipid into a lipid:nucleic acid ccomplex, wherein the non-cationic lipid is a polyethylene glycol-based polymer. Additionally, the instant claims recite wherein the amount of the additional lipid (assuming Applicant is referring to the non-cationic lipid added to the lipid:nucleic acid complex) is from 1 to 15% of the particles, wherein the lipid:nucleic acid is complex is lyophilized, and wherein the nucleic acid is linked to an expression vector to facilitate gene expression after entry into a cell.

5. Claims 1-9, 14-19 and 24-26 of US Patent No. 5,981,501 recite a method for the preparation of serum-stable plasmid-lipid particles, comprising contacting non-cationic lipids with coated plasmid-lipid particles, wherein said method comprises adding a polyethylene glycol-lipid conjugate, and further wherein said polyethylene glycol-lipid conjugate is PEG-Ceramide. It is noted that according to col. 5, lines 53-55, "expression vectors", "cloning vectors", or "vectors" are plasmids or other nucleic acid molecules that are able to replicate autonomously. The method recited in the claims of US Pat No. 5,981,501 do not recite wherein the amount of the additional lipid is from 1 to 15% of the particles or wherein the lipid:nucleic acid complex is lyophilized. However, in a preferred embodiment, col. 11, lines 47-48, of '501 discloses that the concentration of PEG, PEG-ceramide or GMI-modified lipids in the plasmid:lipid particles will be about 1-15%. Additionally, in another specific embodiment of the '501 patent, col. 11, lines 7-11, the plasmid:lipid particles of Wheeler et al. are preferably lyophilized prior to administration. Therefore, although these specific limitations are not recited in the claims, one of ordinary skill in the art at the time of filing would have been motivated to

incorporate these limitations into the claimed invention since these limitations define an obvious variation of the invention claimed in the '501 patent. See MPEP § 804, which states that "[T]hose portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent."

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "the amount of additional lipid." This phrase is vague and indefinite since it is unclear what additional lipid applicants are referring to. It is unclear is the "additional lipid" recited here refers to the non-cationic lipid recited in claim 1, or if it refers to another lipid not recited in claim 1.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
September 30, 2002